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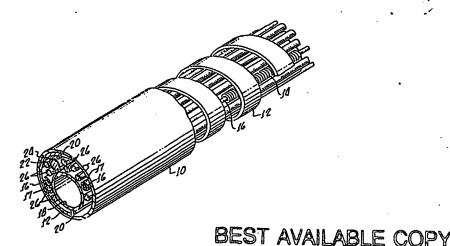
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(54) Title: BI-DIRECTIONAL MINISCOPE



(57) Abstract

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An endoscope has a main portion and a deflecting distal end. The endoscope includes at least one illumination fiber (26) for transmitting light through the endoscope and a viewing fiber (22) assembly. A mainly cylindrical outer spring (12) has a space-wound portion that extends within the deflecting distal end. An outer, mainly flexible, thin-walled protective covering (18) substantially encases the space-wound portion of the outer spring (12). A pair of activation wires (16) extends longitudinally through the endoscope and substantially diametrically opposite each other within the outer spring (12) and, when the endoscope is in an undeflected configuration, lie mainly in a deflection plane. The most distal end of each activation wire (16) is preferably joined to the most distal coil of the outer spring (12) via hypo tube (17). Column support for each activation wire (16) is provided by a closely wound inner spring (14) that is attached to the inner surface of each coil of the outer spring (12).

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BI-DIRECTIONAL MINISCOPE

Field of the Invention

This invention relates to an arrangement permitting two-way movement and control of the distal end of an endoscope.

Background of the Invention

Endoscopes are widely used in many medical procedures for viewing otherwise inaccessible areas of bodily organs, cavities, passageways, etc. Generally, endoscopes include a catheter, or a structure similar to a catheter, in which optical fibers are arranged both for illuminating a viewing area and for carrying the optical image back to the physician. Some form of lens is often attached to the innermost (most "distal") end of the endoscope in order to focus the field of view or illumination of the instrument.

The usefulness of an endoscope is greatly increased when it is provided with some form of control mechanism so that the physician can maneuver the distal viewing end of the scope. First, the ability to maneuver the tip makes it possible for the examining physician to view a much larger area selectively. Ideally, the tip of the scope should even be able to deflect a full 180° so that the physician can "look back" at the site from which the scope Such "retro-viewing" is often desirable, came. example, when examining the puncture site of a gall bladder during a percutaneous procedure. Second, the ability to maneuver the tip makes it easier to guide the tip of the endoscope properly through the often highly branched and convoluted passageways near organs such as the heart.

There are accordingly a large number of endoscopes now available. The following patents show examples of

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existing devices and methods for manufacturing maneuverable catheters, endoscopes, and the like:

	No.	Inventor(s)	<u>Issue Date</u>
5	4,934,340	Ebling et al.	June 19, 1990
	4,911,148	Sosnowski et al.	March 27, 1990
10	4,899,732	Cohen	February 13, 1990
	4,669,172	Petruzzi	June 2, 1987
	4,418,688	Loeb	December 6, 1983
15	3,998,216	Hosono .	December 21, 1976
	3,946,727	Okada et al.	March 30, 1976
20	3,739,770	: Mori	June 19, 1973
20	3,572,325	S. Bazell et al.	March 23, 1971
25	3,610,231	Nagashige Takahashi	October 5, 1971
	3,521,620	W. A. Cook	July 28, 1970

Similar devices are disclosed in the following 30 non-U.S. texts:

U.K. Patent Application No. G3 2 130 885 A (F. A. Coulston-Iles, published June 13, 1984); U. K. Patent Specification No. 1 208 639 (Cook, published October 14, 1970); European Patent Application No. 253 687 (Millar et al., published January 20, 1988); and European Patent No. EP 370 785, (issued to Medical Institute, Inc., 30 May 1990).

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In order to control the deflection of the distal tip of an endoscope, many designs incorporate one or more activation wires that run the length of the endoscope. These are attached to the distal tip, which often is in the form of a stack of hollow rings which are attached to each other and allow pivoting of each ring relative to its neighbor. By pulling on an activation wire, the distal end deflects towards the wire.

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The designer of wire-activated endoscopes is faced with several conflicting requirements. The diameter of the endoscope should be as small as possible so that the endoscope can be maneuvered into the smallest possible passageways and cavities. On the other hand, the outer casing of the endoscope should be as strong as possible to avoid breaking, kinking, and buckling. It should also be stiff to promote the accurate and predictable transmission of torque. At the same time, the activation wire must be able to withstand the tensile load required to deflect the distal end of the endoscope. If, however, the endoscope a mainly solid has either thick outer walls or cross-section, its bending moment will increase and require the activation wire to bear and transmit even greater force in order to deflect the tip. Also, a stiff endoscope will not easily traverse tortuous tracts. Additionally, small-diameter endoscopes have a small moment arm for the activation wire, so that the activation wire must transmit greater force to achieve a given moment.

In order to decrease the diameter of the endoscope, activation wires, if such are even provided, are typically unprotected and are usually welded or soldered directly to the outer casing of the instrument. This arrangement, however, weakens the wires and reduces the bending force they can bear and transmit to the tip. It also increases the risk of buckling not only of the outer casing, but also of the activation mechanism itself. An additional disadvantage of thick-walled designs, or designs having mostly solid cross-section, is that the area left over for carrying illumination and optical fibers, working lumens, etc., is correspondingly decreased.

Additional typical disadvantages of many existing endoscope designs are that they bend only in one direction (which means that the entire scope must be rotated in order to see in the other direction), and that they are

often difficult to manufacture. Furthermore, existing designs that incorporate activation wires typically join these wires to the outer casing of the scope using methods such as soldering or welding that either weaken the wires themselves or decrease the force they are able to bear and transmit.

One object of this invention is therefore to provide an endoscope or "miniscope" that is simple to build, rugged and compact, that avoids the problem of buckling, that has a small outer diameter, and that provides full tip deflection using activation wires that are mounted and joined in such a way that they are able to transfer relatively large activation forces securely.

15 Summary of the Invention

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An endoscope has a main portion and a deflecting distal end. The endoscope includes a viewing fiber assembly and at least one illumination fiber for transmitting light through the endoscope. A mainly cylindrical outer spring has a space-wound portion that extends within the deflecting distal end. An outer, mainly flexible, thin-walled protective covering substantially encases the space-wound portion of the outer spring.

Two-way deflection control is provided by a pair of activation wires that extend longitudinally through the endoscope substantially diametrically opposite each other within the outer spring. When the endoscope is in an undeflected configuration, the activation wires lie mainly in a deflection plane. The most distal end of each activation wire is preferably joined to the most distal coil of the outer spring. Column support for each activation, wire is provided by a hypo tube or alternatively by a closely wound inner spring that is attached to the inner surface of the proximal end of the deflecting section of the outer spring. This construction

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supports a great deal of the compressive force that would otherwise be transferred to the scope body. Thus, buckling and shortening of the scope body are avoided. When either of the activation wires is subjected to a tensile force, the deflecting distal end of the endoscope deflects toward the stressed activation wire; deflection up to about 180° in either direction has been achieved in tests. The maximum achievable deflection may easily be controlled by building a deflecting scope tip of the appropriate length.

Stiffeners in the form, for example, of longitudinally extending wires attached to the inner surface of the space-wound coils of the outer spring may also be provided to establish a plane of maximal rigidity. This promotes deflection of the scope tip in a plane orthogonal to the stiffened plane.

Brief Description of the Drawings

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FIG. 1 is a partially cut-away isometric view of a section of the distal end of an endoscope according to the invention;

FIG. 2 is a simplified illustration of the general outer structure of the endoscope;

FIG. 3 is a cross-sectional view of a deflecting distal end of an endoscope according to one embodiment of the invention, taken along line 3-3 in FIG. 2;

FIG. 4 is a cross-sectional view of the endoscope taken along line 4-4 in FIG. 2 through a portion of the endoscope that is proximal to the deflecting tip; and

FIG. 5 illustrates a preferred method of attaching an activation wire to a supporting sheath structure using crimping.

Detailed Description

FIG. 1 illustrates the general structure of a preferred embodiment of the endoscope according to the

In FIG. 1, the distal end (the end farthest invention. away from the physician) is to the left; the proximal end is to the right. In order to make the internal structure of the endoscope visible, a terminal cap or tip and a portion of the outer tubing (illustrated generally in FIG. 2) have been removed. FIG. 1, therefore, illustrates the most distal end of the endoscope, except for the terminal tip. As is described below, this most distal end is able to deflect under the control of the physician. deflecting, distal end of the endoscope preferably includes an outer covering or tubing 10 that encases an outer spring 12. A column support member 14 encases an activation wire and is point-wise securely attached to the proximal end of the deflecting section of the outer spring 12.

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As FIG. 1 illustrates, the outer spring 12 is preferably a space-wound helical ribbon spring. As is described below, the outer spring 12 not only acts to permit two-way deflection of the distal end of the endoscope, but it also acts as armor to protect the various other fibers, channels, wires and other members that extend within the endoscope. The outer tubing 10 is preferably made of polyetheramide, polyethylene, polyvinylchloride, or some other flexible conventional, biologically inert material, and it is preferably shrunk onto the outer spring 12.

The outer sheath or tubing 10 provides for good torque control, especially if it is well-adhered to the cuter spring 12. Instead of the outer sheath or tubing 10, it is also possible to use counter-wound outer springs. Even triplex springs may be used. The preferred embodiment of the present invention utilizes the outer spring only on the deflecting tip section of the scope. The scope body is made from a stainless steel braid reinforced polymer tube.

As a material, polyethylene has the advantage that the outer tubing 10 can be made with very thin walls (less than 0.003 inches and preferably, approximately 0.002 inches) and high strength. It is not necessary for the 5 outer tubing 10 to be shrunk between the coils of the outer spring 12. The outer tubing 10 may be formed as a smooth cylindrical sheath as long as one takes precaution against the longitudinal stiffness of the material leading to buckling and bunching up on inner radius of a bend. The preferred material for the outer tubing is a soft (60A to 75D, preferably 40D) polyetheramide block copolymer such as Pebax™ available from ATOCHEM with a wall thickness of approximately 0.006 inches. However, it is contemplated as being within the scope of the present invention to utilize flexible polymer tubing having a wall thickness ranging from approximately 0.0005 inches to 0.0015 inches.

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The column support member 14 is preferably either a closely wound inner spring or a continuous tube. column support member 14 (of which there is one for each 20 activation wire 16) provides column support for the activation wires. When the proximal end of an activation wire 16 is pulled, the distal end of the endoscope will deflect towards the pulled wire. Without column support, the scope body might tend to buckle, shorten or form 25 serpentine shapes. (This problem is found in many devices according to the prior art.) The column support member 14 prevents this buckling, and provides for a smooth transition of activation forces to the inner surface of the outer spring 12. The inner diameter of the column 30 support member 14 should be only slightly larger than the diameter of the activation wires 16 in order to eliminate the risk of buckling of the column support while still allowing the activation wires 16 to slide freely within. The activation wires 16 may be made of any material, such 35 as stainless steel wire or bundles of Kevlar fibers, that

has sufficiently high tensile strength to bear the required activation forces.

Running substantially through the length of the endoscope is a working channel or lumen 18. The working channel 18 is provided for the instruments, guide wires, fluids, or other materials that the physician wishes to maneuver within the patient's body through the endoscope. It is an advantage to be able to have as large a working channel 18 as possible; this allows a wider range of uses for the endoscope, while still having the outer diameter of the entire endoscope (the outer diameter of the outer tubing 10) as small as possible to allow it to be inserted into and maneuvered within the smallest possible bodily cavities, passageways, and organs. The structure of this invention allows a large working channel 18 in a small-diameter endoscope. If the endoscope is to be used only for exploratory viewing, the working channel 18 may be deleted; this would allow the endoscope to have an even smaller diameter.

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The most distal ends of the activation wires 16 are, according to the invention, preferably surrounded by additional support members such as the hypo tube 17. In order to enable efficient two-directional bending of the distal end of the endoscope, the activation wires 16 are preferably two in number. The wires 16 thereby define a plane of deflection.

The most distal end of each activation wire is prevented from sliding into its corresponding hypo tube 17 (see below). When one activation wire is pulled, and the other is unstressed and at rest, the outer spring 12 will compress along the side of the pulled activation wire 16 and will therefore deflect towards it.

In order to decrease the tendency of the deflecting end of the endoscope to bend out of the deflection plane, stiffening members 20 are preferably securely attached, for example, by welding, soldering, or other means along

-9-

the space-wound outer spring 12. The stiffening members 20 are arranged in a plane that is perpendicular to the deflection plane. Viewed as in FIG. 1, the activation wires 16 therefore are located at the 3 o'clock and 9 o'clock positions, whereas the stiffening members 20 are at the 12 o'clock and 6 o'clock positions. Since the stiffening members 20 are securely attached to the outer spring 12 at several points, a plane of maximum rigidity is established. This plane is the one which contains both stiffening members. The plane with the least resistance to bending or deflection is that containing the two The hypo tubes, 17 are preferably activation wires. securely attached, for example, by soldering or welding, only to the most distal coil winding or windings of the outer spring 12. The stiffening members 20 will strongly resist any deflections out of the deflection plane. stiffening members 20 may be stiff wires (round or flat) or any other longitudinally rigid member with a high bending moment against any bending out of the deflection plane. The stiffening members 20 should, however, be as light and as small as possible to reduce the bending moment of the deflecting end of the endoscope in the deflection plane.

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The outer spring 12 and outer tubing 10 preferably also enclose and protect a visualization fiber/lens assembly that may include a viewing fiber 22 and a protective sheath 24. The visualization fiber/lens assembly 22, 24 may also include or be attached to a conventional lens or other tip arrangement (not shown).

The visualization fiber 22 will typically include one or more optic fibers so that the physician is able to see the area in the body where the tip of the endoscope is located. The invention also includes one or more illumination fibers 26. Although FIG. 1 shows several illumination fibers, it is also possible according to the invention to use fewer fibers -- even a single fiber --

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for illumination. The number of illumination fibers 26 used will depend on the amount of light needed for the application, and the maximum permissible diameter of the distal end of the endoscope; a single, large-diameter illumination fiber will typically require the inner diameter of the outer spring 12 to be greater than if several smaller fibers are used that, together, have the same cross-sectional area as the single fiber.

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FIG. 2 is a simplified illustration of the general structure of the body of the endoscope that is inserted into the body of a patient. As FIG. 2 shows, the outer structure of the endoscope according to the invention is preferably divided into four main regions: a distal cap or tip 28, a soft, deflecting tip (region D), an unbraided portion (region U), and a braided portion (region B).

The illumination fibers 26, the viewing fibers 22, and the working channel 18 (if included) will normally extend to the surface of the cap or tip 28 which in turn is provided with corresponding ports 36, 38, and 40. Alternatively, the tip 28 may include a lens covering the ends of the illumination fibers 26 and the viewing fibers 22.

The soft, deflecting tip in region D corresponds substantially to the portion of the endoscope shown in FIG. 1. The outer spring 12 (see FIG. 1) preferably does not extend more than a few millimeters into the braided region B. Rather, the braided region B, which includes most of the length of the portion of the endoscope that is inserted into the body of the patient, may have a conventional outer covering to enclose any working channel 18 and the various optic fibers and activation wires that extend through most of the length of the endoscope. An outer, braided, protective layer 30 may be of any conventional type that provides sufficient stiffness to allow the endoscope to be inserted without kinking or buckling into the passageways of the patient's body while

being flexible enough to allow it to negotiate bends in the body's passageways and cavities. The outer braided layer 30 may include reinforcing fibers 32 (see FIG. 4).

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The unbraided region U is a transition region between the braided region B and the soft, deflecting tip D. In the unbraided region U, the endoscope is preferably covered with an outer layer that joins the outer tubing 10 with the outer braided layer 30. The unbraided region U may be very narrow, and may indeed be eliminated altogether provided that the outer spring 12 is then securely attached to the braided outer layer 30. Alternatively, since only the soft, deflecting tip region D requires the outer spring 12 to be spaced-wound, the outer spring 12 may extend into the unbraided region and be closed-wound or even solidly cylindrical in that region.

FIG. 3 is a cross-sectional view of the soft, deflecting tip D of the preferred embodiment of the endoscope according to the invention. This cross-sectional view corresponds roughly to the view shown at the distal end of FIG. 1.

In one prototype of the invention, the outer tubing 10 was made of soft (40 durometer measured on the Shore D scale) Pebax with a thickness of approximately 0.003 inches. The total length of the outer spring 12 was approximately 0.86 inches, and it had an inner diameter of approximately 0.070 inches, with a spacing between the coils on the order of 0.011 inches. In another prototype, a 0.075 inch inner diameter x 0.083 inch outer diameter ribbon spring was used. This left room for a working channel having an inner diameter of 0.043 inches and an outer diameter of 0.052 inches. The stiffening members 20 were steel wire approximately 0.005 inches in diameter and they were point-welded to each coil of the outer spring 12.

In one test, the activation wires were of stainless steel, and wire diameters from 0.005 to 0.007 inches were successfully tested. With an actively deflecting tip length of 0.750 inches, more than 90° of deflection was available in both directions. To support the activation wires at the most distal end, the hypo tubes 17 had an inner diameter of approximately 0.006 inches and an outer diameter of approximately 0.012 inches. The outer diameter of the hypo tubes 17 may be reduced as long as the tubes provide stiffness to support the force imposed by the activation wires 16.

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The supporting hypo tubes 17 preferably extend only for the width of one coil of the outer spring 12. In other words, the hypo tubes 17 serve as encasing end joints between the activation wires 16 and the outer spring 12. FIG. 5 illustrates a preferred method of securing the activation wires 16 in the hypo tubes 17.

The hypo tubes 17 are preferably securely attached to the inner surface of the most distal coil of the outer spring 12 using any conventional method such as welding, soldering, adhesives, etc. Preferably, the hypo tubes will be welded to the outer spring as this produces a very strong bond. The most distal end of the activation wire 16 is then preferably crimped using known methods. The crimped distal end 34 of the activation wire is then not able to pass back through the hypo tube 17. Crimping also produces a very strong bond which exceeds that achievable by directly welding the activation wires to the outer spring.

In one test of a prototype, the hypo tube 17 had an inner diameter of 0.006 inches and an outer diameter of 0.012 inches. Round stainless steel wire with a diameter of 0.005 inches was used as an activation wire. Test crimping was accomplished by one strike of a hammer to create a tapered transition from fully flat to round over a length of about 0.030 inches. For all trials, the

4.50 pounds to 4.86 pounds. This exceeded by a significant margin the force needed to provide at least 90° and up to 180° deflection of the tip, despite the fact that the outer diameter of the prototype endoscope was smaller than most existing designs. The increased ability of the activation wire / hypo tube joint to withstand the tensile forces that arise during operation of the endoscope not only allows the diameter of the endoscope as a whole to be significantly less, without a significant loss of torque, but it also increases the strength and safety of the endoscope as compared with existing designs.

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other methods of connecting the activation wire and the hypo tube may, however, also be used. Screaternatives that were tested included soldering the end of the activation wire 16 to the hypo tube, folding the end of the activation wire over the coil of the outer spring 12 and then welding them together, tying a knot in the most distal end of the activation wire 16 so that the knot could not pass through the hypo tube 17, etc. Other alternatives such as adhesive or crimping the hypo tube itself were also evaluated. Furthermore, both the end of the activation wire 16 and the hypo tube 17 itself may be crimped.

In the preferred embodiment of the invention described above, two activation wires are provided. This embodiment enables a smaller outer diameter than existing devices while still allowing for adequate illumination and a large working channel. The hypo tubes that act as joints between the activation wires and the outer spring efficiently and safely transmit enough bending force to allow at least 60° (and, depending on the particular configuration chosen, up to a full 180°) tip deflection in both directions for a .75 inch tip length. The inner spring (or tube) increases the ability of the activation

-14-

wires to transmit force without buckling of the scope body, so that full torque control can also be achieved.

The column support and hypo tube connection can, however, also be used to improve the performance of endoscopes with only a single activation wire. In such case, the other activation wire may be eliminated and replaced with a mainly flat ribbon stiffener that extends mostly in to the plane of deflection of the tip and is oriented directly opposite the activation wire.

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CLAIMS

1. An endoscope having a main portion, a deflecting distal end attached to the main portion, said endoscope including at least one illumination fiber for transmitting light through the endoscope and a viewing fiber assembly and comprising:

mainly cylindrical outer spring having a space-wound portion extending within the deflecting distal end;

an outer, mainly flexible, thin-walled protective covering substantially encasing the space-wound portion of the outer spring;

a pair of activation wires extending longitudinally through the endoscope and substantially diametrically opposite each other within the outer spring and, when the endoscope is in an undeflected configuration, lying mainly in a deflection plane;

joining means for closely surrounding a most distal wire portion of each activation wire, for joining each most distal wire portion to an inner surface of a most distal coil of the outer spring, and for transmitting tensile forces from each activation wire to the most distal coil of the outer spring; and

for each activation wire, column support means closely encasing the wire within the deflecting distal end portion of the endoscope proximal of the joining means for constraining the wire to move mainly only in the longitudinal direction within the column support means;

whereby, when either of the activation wires is stressed and subjected to a tensile force, the deflecting distal end of the endoscope deflects in the deflection plane toward the stressed activation wire.

35 2. An endoscope as defined in claim 1, further including stiffening means for preventing deflection of

the deflecting, distal end of the endoscope out of the deflection plane.

- 3. An endoscope as defined in claim 2, in which the stiffening means comprises a pair of longitudinal stiffening members that, when the endoscope is in the undeflected configuration, lie mainly in a plane that is perpendicular to the deflection plane.
- 4. An endoscope as defined in claim 1, in which the mainly cylindrical outer spring is a helical metal ribbon with an inner diameter and an outer diameter.
- 5. An endoscope as defined in claim 4, in which the outer diameter of the outer spring is less that 0.090 inches.
- An endoscope as defined in claim 1, in which the activation wires are of steel and have a diameter no greater than 0.007 inches.
 - 7. An endoscope as defined in claim 1, in which the joining means is a mainly rigid, tubular member.
- 8. An endoscope as defined in claim 7, in which the most distal wire portion of each activation wire is crimped to prevent it from sliding into and through the corresponding tubular member.
- 9. An endoscope as defined in claim 1, in which the column support means is a closely wound inner spring that is securely attached to a plurality of coils of the outer spring and that closely encases the corresponding activation wire while still having an internal gap to allow the activation wire to slide freely in the longitudinal direction within the inner spring.

-17-

10. An endoscope as defined in claim 1, in which the outer, mainly flexible, thin-walled protective covering is a flexible polymer sheath having a wall thickness less than 0.0015 inches.

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11. An endoscope as defined in claim 10, in which the sheath is shrunk onto and between the coils of the outer spring.

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12. An endoscope as defined in claim 5, further including a working channel extending longitudinally through the endoscope and within the outer spring, with the inner diameter of the working channel being at least 0.040 inches.

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13. An endoscope having a main portion, a deflecting distal end attached to the main portion, said endoscope including at least one illumination fiber for transmitting light through the endoscope and a viewing fiber assembly and comprising:

mainly cylindrical, helical ribbon outer spring having an inner diameter and an outer diameter and having a space-wound portion extending within the deflecting distal end;

thin-walled flexible, mainly outer, 25 protective covering substantially encasing the space-wound portion of the outer spring;

activation wires pair of longitudinally through the endoscope and substantially diametrically opposite each other within the outer spring undeflected is an endoscope the when configuration, lying mainly in a deflection plane;

a mainly rigid tubular joining member closely surrounding a most distal wire portion of each activation wire, for joining each most distal wire portion to an inner surface of a most distal coil of the outer spring,

-18-

and for transmitting tensile forces from each activation wire to the most distal coil of the outer spring;

stiffening means for preventing deflection of the deflecting, distal end of the endoscope out of the deflection plane, said stiffening means comprising a pair of longitudinal stiffening members that, when the endoscope is in the undeflected configuration, lie mainly in a plane that is perpendicular to the deflection plane; and

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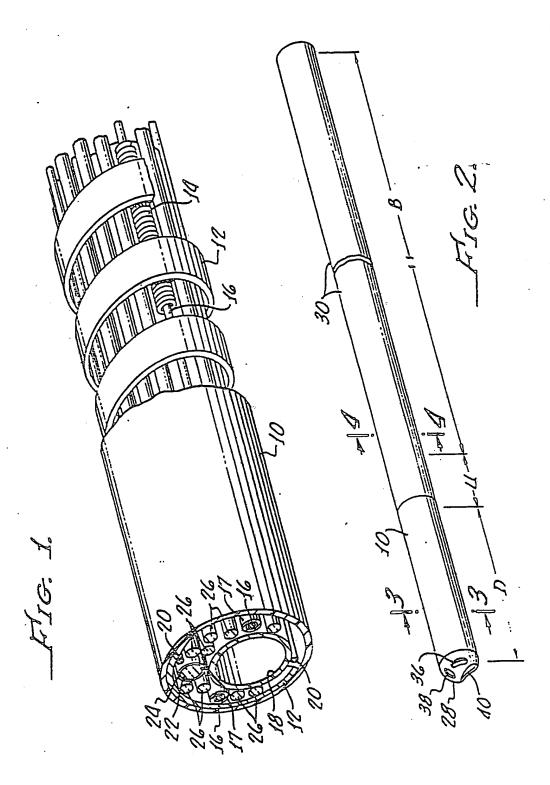
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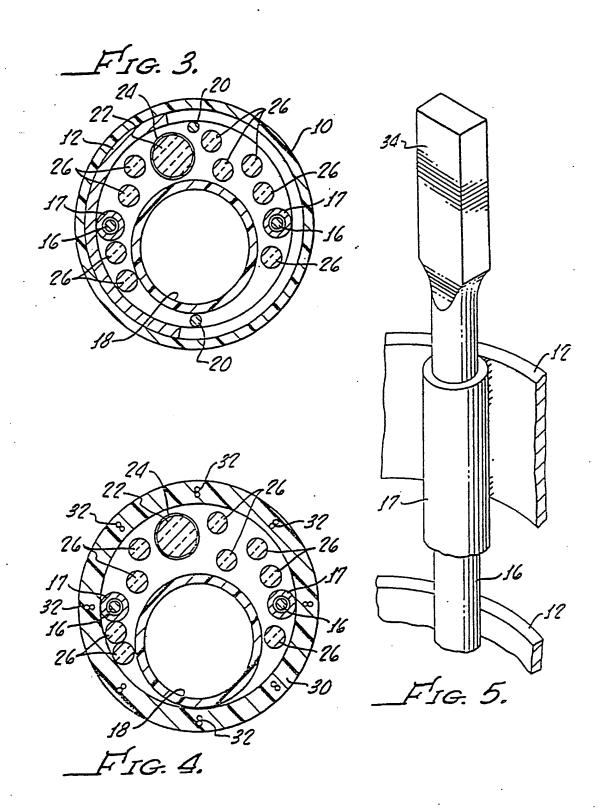
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for each activation wire, a closely wound inner spring that is securely attached to a plurality of coils of the outer spring within the deflecting distal end portion of the endoscope proximal of the tubular joining member and that closely encases the corresponding activation wire for constraining the wire to move mainly only in the longitudinal direction within the inner spring with an internal gap to allow the activation wire to slide freely in the longitudinal direction within the inner spring;

whereby, when either of the activation wires is stressed and subjected to a tensile force, the deflecting distal end of the endoscope deflects in the deflection plane toward the stressed activation wire. 1/2



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INTERNATIONAL SEARCH REPORT

International application No. PCT/US93/00035

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APS: EN	DOSCOPE, SPRING, COLUMN, TORSION		
C. DOC	uments considered to be relevant		
Category	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.
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A	US,A, 3,162,214 (BAZINET, JR) 22 DECEMBER 1964		
	See figure 4, items 24		•
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Box PCT	a, D.C. 20231	KAREN JALBERT	HIGOG-BO

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